Lilly

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Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Draft Guidance on Placing the FDA Therapeutic Equivalence Code on Prescription Drug Labels and Labeling
Docket No. 98D-1266, 64 Fed. Reg. 4434 (January 28, 1999)

Eli Lilly and Company (Lilly) submits these comments on the draft guidance for industry regarding the use on prescription drug labels and in labeling of the therapeutic rating system established in the FDA Orange Book. Although Lilly has other concerns about the draft guidance, its comments in this instance address the issues that arise from a trademark standpoint.

Lilly is one of the world's foremost pharmaceutical companies that, for over 120 years, has been in the business of developing and selling pharmaceutical products. Among its numerous prescription drugs now being marketed are those identified by the trademarks PROZAC, EVISTA, ZYPREXA, HUMALIN, CECLOR, HUMALOG, GEMZAR, and REOPRO, among many others. The trademarks are of incalculable value to Lilly since they serve to identify and distinguish its products from those of others and are a primary way in which professionals and consumers identify the source of medication. While patent protection is important and encourages investments in research and development of new drugs, trademark protection is also important since, both before and after expiration of the patent, it serves as a vehicle whereby professionals and patients can be assured of the source of the medication dispensed.

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The federal trademark law (or Lanham Act) is the statute designed to govern the acquisition and protection of trademark rights. It provides liability for use of a mark which is likely to cause confusion, mistake or deception (15 U.S.C. § 1114) and for use of any term or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which is likely to cause confusion, mistake or deception as to the affiliation, connection or association of the user with another as to the origin, sponsorship or approval of his or her goods, services, or commercial activities (15 U.S.C. § 1125). Section 43(c) of the Act, added in 1996, provides a cause of action for dilution of the distinctive quality of a famous mark.

Lilly believes that implementation of the FDA proposals, particularly concerning use of the market innovator's trademark on generic labels is inconsistent with the goals of the federal trademark law and would cause serious harm to the owners of pharmaceutical trademarks since such use would cause, indeed encourage, confusing, misleading, and diluting use of their trademarks.

Use of the trademark of the pioneer drug on the labeling of a generic creates special problems because of the manner in which prescription drugs are dispensed to the consuming public. There are few other products in which a middleman, in this case the pharmacist, makes the decision as to how the labeling of a product, including the use, if any, of a trademark on that labeling, is to be presented to the ultimate consumer.

In some instances, prescription drugs are dispensed to patients in their original containers, with a pharmacist label affixed in addition to the label from the manufacturer. Lilly is confident in asserting that patients would have no inkling as to the meaning of a phrase such as "This product is AB to TRADEMARK." The presence of the innovator trademark would, in these circumstances, be likely to lead the patient to believe that the generic so labeled is the same as the trademarked product, is from the same source, or is otherwise authorized by or associated with the trademark owner.

In other instances, the pharmacist will take some portion of the pharmaceutical from its original bottle and dispense it in pharmacy bottles, with pharmacy labels only. In such instances pharmacists have broad discretion as to information that will appear on the label and many different practices are followed. The best way to balance the interest of the patient, the generic company, and the pioneer manufacturer is for the generic name only to be used on the pharmacist's labels. If that is done, there is no question that the patient is getting what the physician prescribed. The presence of the

innovator trademark on the labeling of the generic manufacturer's bottles will make it more likely that, when filling the prescription in his own bottles, the pharmacist will include a reference to the innovator trademark on the pharmacy label. There is no control over the manner in which that trademark will be used by the pharmacist and there is a substantial risk that use will be in a manner (e.g. TRADEMARK gen) that will mislead patients into believing that they are receiving the innovator drug and not a generic. In addition, any encouragement of use of the trademark on the pharmacy label, with no control on the manner of use, can result in some use that genericizes the trademark to the great detriment of the trademark owner.

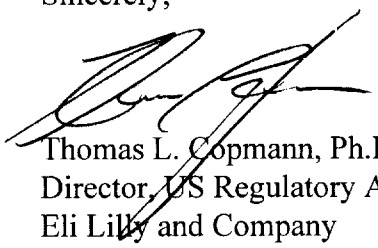
While professionals have more resources than do the patient-consumers to learn the origin of the pharmaceuticals they dispense, Lilly also believes that some may not understand the significance of designations such as AB when they appear on labels, rather than in materials such as the Orange Book where their significance is explained. They too may be confused and the presence of the innovator trademark on the label may lead them to make errors in dispensing. This is likely to occur, for example, when a physician prescribes the innovator drug and requires that it be dispensed as written. Use of the innovator trademark on the generic with a designation as uninformative as AB may lead to dispensing of the generic in error, contrary to the physician instructions.

Trademark law permits fair use of the trademark of another in the comparative advertising context. Use of the mark on the second user's labels, however, particularly when the comparison is expressed in an unclear reference to "AB to TRADEMARK," is more likely to be a misleading, confusing, and deceptive reference rather than one that carries a fair and clear comparative message. For that reason, the dilution statute permits reference to famous marks in comparative "commercial advertising or promotion" but does not refer to such use on product labeling. In advertising and promotion, or in this case in the Orange Book, it is evident that one pharmaceutical is being compared with another. That is not the case, Lilly submits, when the mark is used in the manner contemplated on generic labeling, given the limited space and other constraints. The same limitations, of course, are present on the pharmacy labels used on vials or bottles dispensed to the ultimate consumer.

In these circumstances, Lilly believes that the proposal is inconsistent with the goals of the Lanham Act and will cause incalculable harm to the very valuable and important trademarks used on prescription pharmaceuticals. The goals and interests of both the federal trademark law

and the Food, Drug and Cosmetic Act, however, can be reconciled by continuing with the use of the Orange Book as the medium by which pharmacists are to judge generic equivalence.

Sincerely,



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